REMARKS

Claims 13-26 have been canceled without prejudice or disclaimer. Claims 27-39 have been added and therefore are pending in the present application. Claims 27-39 are supported throughout the specification, including the original claims. For example, the temperature and pH optima recited in claims 29, 33 and 38 are supported by page 7, line 28 – page 8, line 3 of the specification.

The specification has been amended to update the Cross-Reference to Related Applications section and to remove hyperlinks, as requested by the Examiner.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 13-19 and 22-26 under 35 U.S.C. 112

Claims 13-19 and 22-26 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. This rejection is respectfully traversed.

It is well settled that "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter ..." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). In fact, "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly and Co.*, 43 U.S.P.Q.2d at 1569.

Applicants submit that the application as originally filed reasonably conveys to the artisan that the inventor had possession of the claimed subject matter.

The present invention relates to methods for improving the nutritional value of an animal feed or a vegetable protein, comprising adding an acid-stable protease that comprises an amino acid sequence having an identity of at least 90% to SEQ ID NO: 1 or an acid-stable

Nocardiopsis protease. Applicants have demonstrated that acid-stable proteases have a significantly better effect on protein solubilization in animal feed which leads to an improved nutritional value of the feed.

In the claims at issue, the sequence identity is high, *i.e.*, at least 90% and 95% identity to SEQ ID NO: 1, or the protease is an acid-stable *Nocardiopsis* protease. Given such high degree of sequence identity, an artisan would reasonably expect that the proteases encompassed by the claims share a high degree of structural and functional similarity. Since the claimed structural features provide a correlation between function and structure, the written description requirement is satisfied.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 13-19 and 22-26 under 35 U.S.C. 103

Claims 13-19 and 22-26 are rejected under 35 U.S.C. 103 as being unpatentable in view of Bedford et al. (WO 96/05739) in view of Snow-Brand-Milk-Prod. (JP 02255081). This rejection is respectfully traversed.

Snow-Brand-Milk-Prod. merely disclose a *Nocardiopsis* protease. However, Snow-Brand-Milk-Prod. do not teach or suggest the use of proteases in animal feed.

Bedford et al. disclose feed additives comprising a xylanase and a protease and optionally a beta-glucanase. At page 25, Bedford et al. discloses that the protease may be one of the following commercially available proteases: NEUTRASE™, PURAFECT™, SAVINASE™, MAXACAL™, DURAZYM™ and MAXAPEM™, or a mutant subtilisin described in one of a number of published patent applications. None of the proteases described in Bedford et al. is an acid-stable protease according to the present invention.

The feed additives described in Bedford et al. are said to have an improved (i.e., lower) feed conversion ratio (FCR), which results in more efficient utilization of the feed. However, the results shown in Bedford et al. do not prove Bedford et al.'s allegations of improved FCR.

The only experiments using a protease described in Bedford et al. are provided in Examples 2 and 5.

In the experiment described in Example 2, chickens were treated with a control animal feed (with no enzymes), an animal feed designated "Z", which is identical to the control except that it also contains xylanase, three animal feeds designated "A," "C," and "E", which are identical to Z except that they contain the protease NEUTRASE™, and three animal feeds designated "B," "D" and "F",

which are also identical to Z except that they contain a modified *Bacillus amyloliquefaciens* subtilisin protease.

The results, which are provided in Table 4, show that the use of the control animal feed and the animal feed designated Z resulted in an FCR of 1.85, the use of the animal feeds designated A, C and E resulted in an FCR of 1.85, 1.85 and 1.82 (i.e., two of the animal feeds containing the protease NEUTRASE™ resulted in the same FCR as the control animal feed and the animal feed designated Z), and the use of the animal feeds designated B, D and F resulted in an FCR of 1.82, which is only a fraction below the FCR obtained with the control animal feed and the animal feed designated Z. There is no statistical difference between the results obtained using the control animal feed and the animal feed designated Z, on the one hand, and the results obtained using the animal feeds designated A-F, on the other hand. Thus, the results of Example 2 would not suggest to one of ordinary skill in the art that there is an improvement in FCR by using a protease in an animal feed.

Similarly, the results in Example 5 shown in Table 9, do not demonstrate that there is any statistical difference between using a protease-free animal feed and a protease-containing animal feed. Thus, the results of Example 5 also would not suggest to one of ordinary skill in the art that there is an improvement in FCR by using a protease in an animal feed.

On the other hand, the instant application demonstrates in Example 4 that the protease of SEQ ID NO: 1 (*Nocardiopsis sp.* NRRL 18262 protease) has a statistically and significantly better effect on protein solubilization. An artisan would not expect based on Bedford et al. that the proteases recited in the present claims would improve the nutritional value of feed. Therefore, the results provided in the specification are surprising and unexpected, especially when considering the thousands of proteases that are known in the art.

Applicants enclose a copy of a Declaration under 37 C.F.R. 1.132 of Carsten Sjøholm, which was filed during prosecution of the parent application. Mr. Sjøholm explains that the results disclosed in the Bedford et al. do not prove to one of ordinary skill in the art that the addition of a protease to an animal feed results in an improved feed conversion ratio and that the results disclosed in the instant application show that the *Nocardiopsis* protease of SEQ ID NO: 1 has a significantly better effect on protein solubilization in animal feed which leads to an improved nutritional value of the feed. Mr. Sjøholm concludes that these results are surprising and unexpected, especially when considering the thousands of proteases that are known in the art.

Applicants also enclose a copy a Declaration under 37 C.F.R. 1.132 of Anna-Maria Klünter, which was also filed during prosecution of the parent application. The Klünter declaration describes

a set of experiments in which chickens were fed feed compositions with or without the *Nocardiopsis* protease of SEQ ID NO: 1. Dr. Klünter reports that the results of the experiments "clearly demonstrate that broiler chickens have a significantly improved weight gain and significantly improved feed conversion when fed an animal feed composition comprising the *Nocardiopsis* protease." Dr. Klünter also concludes that the results are surprising and unexpected.

These results demonstrate that broiler chickens have a significantly improved weight gain and significantly improved feed conversion when fed an animal feed composition comprising an acid-stable protease. The acid-stable proteases recited in the claims differ significantly in structure (low identity) and function (acid stability) from the proteases of Bedford et al. Based on the general knowledge in the art and in particular, Bedford et al., an artisan would not expect that all proteases are suitable for use in feed let alone that the acid-stable proteases recited in the claims of the present invention would be useful for improving the nutritional value of feed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 20 and 21 under 35 U.S.C. 101

Claims 20 and 21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4-5 of prior U.S. Patent No. 6,855,548. Claims 20 and 21 have been canceled without prejudice or disclaimer. Therefore, this rejection is rendered moot.

IV. The Rejection of Claims 13-19 and 22-26 under the Doctrine of Obviousness-Type Double Patenting

Claims 13-19 and 22-26 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of U.S. Patent No. 6,855,548.

Applicants will file a terminal disclaimer upon an indication of allowable subject matter.

V. The Rejection of Claims 13-18 and 22-25 under the Doctrine of Obviousness-Type Double Patenting

Claims 13-18 and 22-25 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 18-19 of U.S. Patent No. 7,179,630 "since the claims, if allowed, would improperly extend the 'right to exclude' already granted in the patent." This rejection is respectfully traversed.

U.S. Patent No. 7,179,630 issued from U.S. Application No. 10/873,593 filed June 21, 2004. There was no patent term adjustment as a result of delays during the examination by the U.S. Patent and Trademark Office. Thus, U.S. Patent No. 7,179,630 expires on June 21, 2024.

The instant application is a continuation of U.S. Application No. 09/779,323 filed February 8, 2001. Since Applicants agree to file a terminal disclaimer over U.S. Patent No. 6,855,548 upon an indication of allowable subject matter, a patent issuing from this application will expire on February 8, 2021, *i.e.*, more than three years prior to the expiration of U.S. Patent No. 7,179,630. Thus, the claims, if allowed, would not extend the 'right to exclude' already granted in U.S. Patent No. 7,179,630.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under the doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 13-26 under the Doctrine of Obviousness-Type Double Patenting

Claims 13-26 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Application No. 10/544,861.

U.S. Application No. 10/544,861 is a national phase application of international application no. PCT/DK2004/000090 filed February 9, 2004. Assuming there are no delays during the examination by the Office of U.S. Application No. 10/544,861, a patent issuing therefrom will expire on February 9, 2024.

As stated above in Section V, a patent issuing from this application will expire on February 8, 2021, *i.e.*, about three years prior to the expiration of U.S. Patent No. 7,179,630. Thus, the claims, if allowed, would not extend the 'right to exclude' of any patent issuing from U.S. Application No. 10/544,861.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under the doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: February 15, 2008

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